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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,099	12/17/2001	Frank Himmelsbach	5/1310	2352

28501 7590 10/10/2003

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 10/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

10/023,099

Applicant(s)

HIMMELSBACH ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on th cover sheet with the c rrespondence address --

**Period f r Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Pri rity under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

### DETAILED ACTION

It is noted that the filing date of the Provisional Application No. 60/259,201 listed in the specification (12-18-2000) is inconsistent from the filing date shown in USPTO's record (12-28-2000).

Claims 1-19 are pending.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. Claims 1-7 recite the limitation of "tautomer" which has indefinite metes and bounds because it is not clear if the "tautomer" of the side chain (i.e., keto-enol) is intended, or the "tautomer" between the ring nitrogen and the amino substituent (i.e., amine-imine) is intended.
- b. Claims 1-7 also recite "salt thereof" which also has indefinite metes and bounds because it is unclear if 'physiologically unacceptable salt' is included. Applicant is suggested to insert 'pharmaceutical' in front of "salt thereof".

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c. Claims 8-10 recite “physiological acceptable salt” which is not recited in the claims they depend on.

d. Claims 11-19 are rejected as being dependent on anyone of claims 1-7, and carry on their limitations.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Scope of Enablement:** Claims 17-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of benign tumors that are linked to the activity of EGF-R kinase, does **not** reasonably provide **enablement** for the treatments of other diseases such as: **malignant tumors, airways and lungs, GI tract, bile duct, gall bladder**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

- (1) The breadth of the claims;
- (2) The amount of direction or guidance presented;
- (3) The state of the prior art;

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- (4) The relative skill of those in the art;
- (5) The predictability or unpredictability of the art;
- (6) The quantity of experimentation necessary

[See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

**The breadth of the claims:** The claims call for the treatment of various diseases that affect different organs and tissues, and have unrelated etiologies. For example, malignant tumors do not share the same origin, and have different growth pattern. Likewise, airways and lungs diseases do not have the same receptors as those in the GI tract. As for bile duct and gall bladder, the major causative factor is gallstones which are often required surgical removal. Therefore, it is inconceivable as to how one therapeutic agent can treat diseases as diversified as claimed herein.

**The amount of direction and guidance presented:** Only a few compounds are tested for the inhibition of EGF-R kinase (or Epidermal Growth Factor-Receptor kinase), which is an enzyme used in the phosphorylation of EGF-R. From said testing, the specification draws the conclusion that the claimed compounds can “*inhibit signal transduction by tyrosine kinases.*” However, EGF-R kinase and tyrosine kinases are two different kinds of enzyme. Thus, for a compound to inhibit EGF-R kinase, it does not mean it can inhibit the activity of tyrosine kinases. There is no structural similarity between the two kinds of kinases that could support such a conclusion. Therefore, to extend the use of the claimed compounds to the treatments of other diseases that are related to tyrosine kinases, it would require undue experimentation.

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**State of the prior art:** Many teachings in the art (as evident by the references cited on the IDS) do not equate EGF-R kinase with tyrosine kinases. The term 'EGF-receptor kinase' does not specifically mean "tyrosine kinases".

Thus, with the broad scope of the claims, limited guidance provided, and **unpredictable nature of the art**, one skilled in the art would have to carry out undue experimentation to practice the claimed method in a clinical setting.

### ***Double Patenting***

The **nonstatutory** double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 17-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10/ 353,616 (US 2003/0149062 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a method for treating diseases of airways, lungs, and intestines (or gastrointestinal tract)

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comprising the administering an effective amount of a similar quinazoline compounds. That is, quinazoline compound in US'062 overlaps with the claimed compound when it has the following substituents:

X is N;

R<sup>a</sup> is hydrogen, while R<sup>b</sup> has the same scope as the instant R<sup>a</sup>, and R<sup>c</sup> has the same scope as the instant R<sup>c</sup>;

A is imino; B is carbonyl, and C is ethenylene;

n = 1;

D is dimethylamino, diethylamino, or morpholino (corresponding to the instant R<sup>b</sup>).

Also see compounds #6-8 in claim 4, and compound #18 in claim 5 of US'062

4. The method claimed in US'062 does not overlap with the instant method when X is carbon substituted with a cyano group, and A-D represents other moieties. Also, in US'062, the method using a substance from items (b)-(d) does not overlap with the instant method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (7 am -12 pm, and 3 pm - 6 pm) starting from 10-1<sup>st</sup> -03).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



T. Truong

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October 9, 2003



ALAN L. ROTMAN  
SUPERVISORY PATENT EXAMINER  
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